# PATENT COOPERATION TREATY

	From the INTERNATIONAL BUREAU		
PCT	To:		
NOTIFICATION OF FLECTION			
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Assistant Commissioner for Patents United States Patent and Trademark Office Box PCT		
	Washington, D.C.20231 ÉTATS-UNIS D'AMÉRIQUE		
Date of mailing (day/month/year) 10 March 2000 (10.03.00)	in its capacity as elected Office		
International application No. PCT/US99/12959	Applicant's or agent's file reference CM1987Q/VB		
International filing date (day/month/year) 11 June 1999 (11.06.99)	Priority date (day/month/year) 26 June 1998 (26.06.98)		
Applicant D'ACCHIOLI, Vincenzo et al			
1. The designated Office is hereby notified of its election made    X   in the demand filed with the International Preliminary   12 January 200   in a notice effecting later election filed with the International Preliminary   12 January 200   in a notice effecting later election filed with the International Preliminary   2. The election   X   was   was not   was n	Examining Authority on:  00 (12.01.00)  ational Bureau on:		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

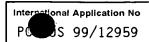
Juan Cruz





(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference CM1987Q/VB	FOR FURTHER see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.					
International application No.	International filing date (day/mon	h/year) (Earliest) Priori	ty Date (day/month/year)			
PCT/US 99/12959	11/06/1999		26/06/1998			
Applicant THE PROCTER & GAMBLE COMP	ANY et al.					
This International Search Report has been according to Article 18. A copy is being to This International Search Report consists	ansmitted to the International Burea		nitted to the applicant			
1 177	/ a copy of each prior art document					
Basis of the report     a. With regard to the language, the language in which it was filed, ur	international search was carried ou lless otherwise indicated under this		onal application in the			
the international search (Authority (Rule 23.1(b)).	was carried out on the basis of a trai	nslation of the international ap	pplication furnished to this			
was carried out on the basis of the contained in the internation	b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:  contained in the international application in written form.  filed together with the international application in computer readable form.					
	o this Authority in computer readble	form.				
the statement that the su	bsequently furnished written sequer as filed has been furnished.		d the disclosure in the			
the statement that the inf furnished	the statement that the information recorded in computer readable form is identical to the written sequence listing has been					
	und unsearchable (See Box I).					
3. Unity of invention is lac	cking (see Box II).					
4. With regard to the title,						
	ubmitted by the applicant.					
1 55	shed by this Authority to read as foll	ows:				
5. With regard to the abstract,						
the text has been establi	ubmitted by the applicant. shed, according to Rule 38.2(b), by e date of mailing of this internationa	this Authority as it appears in I search report, submit comm	Box III. The applicant may, ents to this Authority.			
6. The figure of the <b>drawings</b> to be put  as suggested by the app  X because the applicant fa  because this figure bette	licant.	o. <u>1</u>	None of the figures.			



A.	CLA	SSIFIC	ATION	OF	SUBJEC1	MATTER
TE	7	6	<b>161E</b>	T = /	1/1/12	

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUME	NTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
Χ	EP 0 753 290 A (HOLLISTER INC) 15 January 1997 (1997-01-15)		1,3-5, 7-9
Y	column 7, line 6 - line 41; figures		2,6
Ϋ́	US 3 759 260 A (NOLAN J ET AL) 18 September 1973 (1973-09-18) column 4, line 47 - line 68; figures 8,9		2
Υ	US 3 368 561 A (ERICSON RICHARD E ET AL) 13 February 1968 (1968-02-13) column 2, line 30 - line 36; figures 1,2		6
X	DE 16 16 144 A (DIPPEL) 15 April 1971 (1971-04-15) page 3, line 18 -page 4, line 7; claim 3; figures	·	1,3,5,9
•	-/ <del>-</del> -		•

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
<ul> <li>Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier document but published on or after the international filing date</li> <li>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> </ul>	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
7 October 1999	14/10/1999
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sánchez y Sánchez, J

1



	nuation) DOCUMENTS CONSIDERED TO BE RELEVANT					
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
4	US 4 784 656 A (CHRISTIAN DELORES J) 15 November 1988 (1988-11-15) column 4, line 59 - line 65; figure 5		1,7,9			
	GB 1 074 344 A (HOLLISTER) 5 July 1967 (1967-07-05)					
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form on patent family members

International Application No
PC 99/12959

Patent document cited in search repo		Publication date	Patent family member(s)	Publication date	
EP 0753290	Α	15-01-1997	US 5593397 A CA 2176782 A	14-01-1997 14-01-1997	
US 3759260	A	18-09-1973	BE 804946 A CA 1007127 A DE 2236455 A DK 135303 B FR 2153901 A GB 1379464 A JP 48037981 A JP 52027949 B US 4355379 A	16-01-1974 22-03-1977 29-03-1973 04-04-1977 04-05-1973 02-01-1975- 04-06-1973 23-07-1977 19-10-1982	
US 3368561	A	13-02-1968	NONE		
DE 1616144	Α	15-04-1971	NONE		
US 4784656	Α	15-11-1988	NONE		
GB 1074344	Α		NONE		

# PATENT COOPERATION TREATY

**PCT** 

REC'D 18 SEP 2000

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

_Applicant's	or age	nt's file reference			cation of Transmittal of International		
CM1987Q/VB			FOR FURTHER AC	TION Prelimina	y Examination Report (Form PCT/IPEA/416)		
International application No. Inte			International filing date (c	lay/month/year)	Priority date (day/month/year)		
PCT/US9	9/12	959	11/06/1999		26/06/1998		
Internationa A61F5/44		nt Classification (IPC) or nat	tional classification and IPC				
Applicant							
THE PRO	CTE	R & GAMBLE COMP	ANY et al.				
		ational preliminary exami smitted to the applicant a		prepared by this In	ternational Preliminary Examining Authority		
2. This F	REPO	RT consists of a total of	7 sheets, including this	cover sheet.			
b (\$	This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheets.						
ı	⊠	contains indications rela	iting to the following iter	ns:			
11		Priority	mining with record to po	welty inventive ste	n and industrial applicability		
III IV		Lack of unity of invention		ivelly, inventive ste	p and industrial applicability		
v	⊠	Reasoned statement u		egard to novelty, in ement	ventive step or industrial applicability;		
VI		Certain documents cit	ed				
VII	$\boxtimes$	Certain defects in the in	nternational application				
VIII	⊠	Certain observations o	n the international appli	cation	•		
Date of sut	missi	on of the demand		Date of completion	of this report		
12/01/20	00			13.09.2000			
	exam Euro D-8 Tel.	g address of the international ining authority: opean Patent Office 0298 Munich +49 89 2399 - 0 Tx: 52365		Authorized officer  Ardhuin, H	80 2290 7511		

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/12959

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):
Description, pages:

	Des	cription, pages:	
	1-20	)	as originally filed
	Clai	ims, No.:	
	1-9		as originally filed
	Dra	wings, sheets:	
	1/3-	3/3	as originally filed
2.	The	amendments hav	re resulted in the cancellation of:
		the description,	pages:
		the claims,	Nos.:
		the drawings,	sheets:
3.			een established as if (some of) the amendments had not been made, since they have been beyond the disclosure as filed (Rule 70.2(c)):
1	Δdc	litional observation	ns if nacassany

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/12959

V. Reasoned stat m int under Articl 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

# 1. Statement

Novelty (N)

Yes: No: Claims 2-4,6

1115 2

Claims 1,5,7-9

Inventive step (IS)

Yes: No: Claims

Claims 2-4,6

Industrial applicability (IA)

Yes:

Claims

No: Claims 1-9

2. Citations and explanations

see separate sheet

#### VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

#### VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

# **EXAMINATION REPORT - SEPARATE SHEET**

#### Re It m V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty and inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents, cited in the international search report:

D1: EP - A - 0 753 290

D2: US - A - 4 784 656

D3: US - A - 3 368 561

D4: DE - A - 16 16 144

# V.1. Independant claims

Claim 1 defines a "urine management device".

The document D1 discloses (D1, col. 3, line 33 - col. 4, line 7 and col. 7, lines 38-41) a device comprising all technical features defined in claim 1. The two devices according to D1 and to claim 1 are expressly used for different purpose: D1 relates to a "faecal collector" while claim 1 defines a urine collector. However, this does not imply differences between the technical features of the two devices and therefore the subjectmatter of claim 1 is not new in the sense of Article 33 (2) PCT (see also PCT Guidelines C, IV, 7.6). D4 (p. 3, l. 18- p. 4, l. 4).

Claim 7 relates to a method for placing the urine management device according to claim 1. This method comprises three steps. The two first steps are of common general practice as described in the present application, p. 1, last paragraph. The third step refers to the use of the non-adhesive lobe to manipulate the device. This is not expressly disclosed in document D1. However, it is technically sensible to grasp these non-adhesive lobes which are close to the flange in order to place the device: this step is implicitly disclosed in document D1. Therefore the subject-matter of claim 7 is not new in the sense of Article 33 (2) PCT (see also PCT Guidelines C, IV, 7.2).

In any case, the grasping of such non-adhesive lobe attached to an adhesive releasable element is common practice in the art, in order to achieve precise positioning of the adhesive element on the surface it has to stick to, (see for example document D2).

Document D1 discloses (col. 7, lines 38-59) all steps of the method defined in independant claim 9 for the removal of the device. Hence the subject-matter of claim 9 is not new in the sense of Article 33 (2) PCT. D4 (p. 3, I. 18- p. 4, I. 4).

# V.2. Dependant claims depending on claim 1

Document D1, considered as the closest prior art, describes a device with only one lobe while claim 2 states that at least two lobes are comprised in the urine management device. This multiplicity of lobes achieves the following technical effects: grasping of the lobes by the caretaker with the two hands and some choice in the position of its hand(s) relative to the device and the patient when placing or removing the device. Several lobes have already been employed to achieve such effects in a similar device, see document D2, col. 6, lines 6-14. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a urine or faecal collector according to document D1, thereby arriving at a urine management device according to claim 2. The subjectmatter of claim 2 does not, therefore, seem to involve an inventive step (Article 33(3) PCT).

Claim 3 specifies the position of the lobe relative to the flange of the urine management device (in case there is only one lobe). Document D1 does not give any precision about this position. When interpreting the term "upward" in the sense given p. 14 of the description (see here above, item VIII), this position is more easily accessible by the caretaker when removing the device from the uro-genital area of a wearer, due to the room taken by its legs. The choice of this position comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance. Consequently, the subject-matter of claim 3 appears to lack an inventive step (Article 33(3) PCT).

Claim 4 specifies the positions of the lobes relative to the longitudinal axis of the flange (see item VIII bellow), in case there are at least two lobes. Such positions allow a more precise positioning of the device by the caretaker when placing the device in the urogenital area of a wearer, since the flange has to be curved around its longitudinal axis in order to fit the wearer. The choice of these positions comes within the scope of the customary practice followed by persons skilled in the art, because the advantages thus

achieved can be readily contemplated in advance. Consequently, the subject-matter of claim 3 appears to lack an inventive step (Article 33(3) PCT).

Document D1 also describes the release means defined in **claim 5**. Therefore the features of claim 5 are not new within the meaning of Article 33 (2) PCT.

The additional features of the release means as defined in **claim 6** is known from document D3 and employed therein to achieve the same effect as in the present application: to facilitate the removal of the release means. Hence it would obvious to the person skilled in the art, namely when the same result is to be achieved, to combine these features known form D3 with the device according to D1. Therefore the subject-matter of claim 6 does not involve an inventive step (Article 33(3) PCT).

# V.3. Dependant claim 8, depending on claim 7

Claim 8 relates to an additional step, for placing a urine management device, which is needed when the device comprises the release means defined in claim 5. Such device with release means is known from D1 and this additional step is described therein (D1, col. 7, 14-37). Therefore, the subject-matter of **claim 8** is not new (Article 33 (2) PCT).

# V.4. Industrial application

Industrial application is self-evident. Thus, the claims appear also to fulfil the requirements of Article 33 (4) PCT.

#### Re Item VII

# Certain defects in the international application

#### VII.1. Dependency of claim 8

It seems that claim 8 should relate to the method of claim 7 (rather than "the method of claim 8").

#### VII.2. Two part form

Independent claims 1, 7 and 9 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule

6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

# VII.3. Acknowledgement of background art documents

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

# Re Item VIII

# Certain observations on the international application concerning clarity

VIII.1. The term "upward" used in claim 3 is defined in the description p. 14 as having a particular meaning within the application and the subject-matter of claim 3 is therefore not clear from the wording of the claim alone (Rule 10.1 (e) PCT and PCT Guidelines C, III, 4.2). In the present International Report, the subject-matter of claim 3 has been interpreted in the light of the definition of upward given p. 14.

VIII.2. In claim 4, the positions of the lobes relative to the "longitudinal axis" of the device is defined, while these positions are defined relative to the longitudinal axis of the flange in the description. Hence the subject-matter of claim 4 lacks consistency with the description (PCT Guidelines C, III, 4.3). In this application these two axes are one and the same but it is not the case in some prior art documents (see for example D1 in which the longitudinal axis of the device extends from the element 13 to the centre of the flange). Therefore claim 4 should clearly refer to the longitudinal axis of the flange. In the f present International Report, claim 4 has been examined as defining the position of the lobes relative to the longitudinal axis of the flange, as in the description.